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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/015,365

12/13/2001

Bruce Robie

Implex-18

2786

28581

7590

05/04/2006

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EXAMINER

STOKES, CANDICE CAPRI

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,365

Applicant(s)

ROBIE ET AL.

Examiner

Candice C. Stokes

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,9-13,15-17,19-21,23,25-27,29-33,35-37 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,9-13,15-17,19-21,23,25-27,29-33,35-37 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 3, 10, 11, 13, 20, 21, 23, 30, 31, 33, 40, 45 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Aebi et al (6,482,233). Aebi shows a device comprising a body having upper and lower surfaces separated by curved side surfaces (Figure 2), which extend between a posterior end 12 of the body to an anterior end 14 of the body. A first plurality of teeth 22 extend across the upper surface. The first teeth are disposed in a first plane and angle back toward the anterior end of the body. A second plurality of teeth 24 extend across the lower surface. The second teeth are disposed in a second plane and angle back toward the anterior end of the body. The body has a thickness between the first and second planes that continuously decreases from the anterior end to the posterior end (see Figure 4). As to the recitation that the device is for distracting a disc space and simultaneously preparing the endplates, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re*

Art Unit: 3732

0:0, 136 USPQ 458, 459 (CCPA 1963). As to claims 3, 13, 23, 33, note that an inserter may be removably coupled to the body via holes 30 (column 5, lines 11-12). As to claims 11, 31, 46 note that the device may come in a plurality of sizes (column 5, lines 48-55 and column 6, lines 13-15). As to claims 21, the teeth are considered to be ratcheting because they are formed to prevent the device from backing after insertion (column 4, lines 30-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 9, 19, 29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233). Aebi discloses the claimed invention except for the angle of taper being about 7 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the taper with an angle of about 7 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2) Claims 5-7, 15-17, 25-27, 35-37 and 41-44, are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233) in view of Coates et al (5,989,289). The teeth of Aebi are not formed in the shape set forth in the claims. Coates shows a device 400 of the same type as Aebi having a plurality of teeth on the upper and lower surfaces. The teeth include

anterior wedge surfaces 460 and posterior shovel surfaces 455 that intersect to form cutting edges 480, and arcuate root surfaces 470. This forms a pocket between the surfaces, which trap the vertebral bone and prevent migration of the device (column 3, lines 56-62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the teeth of Aebi as taught by Coates, in order to prevent migration of the device after implantation.

3) Claims 12, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233) in view of Ralph et al (2003/0014113). Aebi does not teach that the body of the devices having an incrementally different average body thickness. Ralph shows a device of the same type as Aebi and teaches that plurality of sequentially devices may be provided to sequentially distract the intervertebral space to ensure an anatomically correct spinal configuration (paragraph 0024). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the bodies of Aebi having incrementally different average body thicknesses, in view of Ralph, in order to sequentially distract the intervertebral space to ensure an anatomically correct spinal configuration.

Response to Arguments

Applicant's arguments filed 02/21/06 have been fully considered but they are not persuasive. The Applicant submits "the Aebi patent fails to disclose, either expressly or inherently, the *undercut* limitation. Rather, the Aebi patent shows pyramidal shaped teeth (spikes) 28" (see page 11, 1st paragraph). The Office asserts that the Aebi patent does disclose the claimed invention and the undercut limitation, newly added to the claims. First, the portion of the amended claims, which recites, "to provide each of the teeth with an undercut", is a

Art Unit: 3732

recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further, the Aebi patent only shows pyramidal shaped teeth in Figure 7, which is an end view of the claimed invention. The side views (see figures 4 and 6) of the claimed invention shows the teeth angled back providing an undercut. Further to the amendments to claims 41-44, the terms “anterior” and “posterior” are relative to viewpoints and are interchangeable as shown by the present amendment. Clearly, rotating an apparatus, anterior becomes posterior and posterior becomes anterior. Thus, the aforementioned rejections are upheld.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714.


The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Candice C. Stokes


PATRICIA BIANCO
PRIMARY EXAMINER
5/1/06